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MidTerm Overall Evaluation Report

PROPOSAL: 2000000049
TITLE: LRMC Remote Nerve Fiber Laser Analysis and Teleophthalmology Project

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ACCOMPLISHMENTS

Submitted modified protocol to the Walter Reed Army Medical Center Institutional Review Board (local IRB) where the Human Use committee approved the protocol for human use exemption. Since we chose to use pre-existing data, full human use approval was not needed. The protocol was also submitted to the HSRRB at Ft. Detrick, Maryland and approved for human use exemption status.

Three glaucoma specialists from Military Treatment Facilities in CONUS were briefed on the protocol and volunteered to participate in the study as our "consultants".

The main part of the study was completed with the emailing and postal mailing of Gdx images and questionnaires to the three glaucoma specialists.

Please see modifications to proposal in "problems" section for details.

PI's Accomplishment Evaluation: : Project accomplishments are close to proposal

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PROBLEMS

There was a significant time delay in starting the study due to protocol approval issues. The initial proposal planned to use patients prospectively. Due to time constraints and operational tempo of the clinic it would have been impossible to design and submit a protocol for full human use consideration and still keep within the study deadlines. For this reason the proposal was modified. The purpose of the study was to determine if the equipment (Gdx Nerve Fiber Layer analyzer) purchased with telemedicine funds could be used efficiently and effectively in a telemedicine scenario. The usefulness of the Gdx in clinical ophthalmology has already been proven in the FDA studies. The Gdx is being used in our clinic on a routine basis in the evaluation of patients with suspected glaucoma. The modified protocol describes using preexisting patient data (Gdx images/printouts) that had been obtained in our clinic and saved in the hard drive of the Gdx computer prior to beginning this telemedicine study. The pre-existing Gdx data with patient identifiers removed was used in this study. The Gdx data (printouts) from 30 eyes was sent to three glaucoma specialists via Outlook (world wide web). In addition the same 30 Gdx images were printed on paper as hard copies and sent via the US postal service to each of the three glaucoma specialists. Excerpts from the approved protocol are pasted below to elaborate on study design.

Proposal modification: OBJECTIVES: To test the efficacy and efficiency of transmitting digital nerve fiber layer analysis results via e-mail for teleconsultation. PLAN: a. Subjects: Retrospective review of pre-existing Nerve Fiber Layer Analysis images (hereafter referred to as Gdx images). No patients will be used. No direct or indirect patient identifiers will be use. Human use review exemption will be requested b.Inclusion and Exclusion Criteria: 30 random Gdx images of 30 different optic nerves from 30 different patients (30 images total) will be printed from the hard drive of the Gdx computer by an ophthalmic technician not associated with the study. c.Study Design: Retrospective study using pre-existing Gdx images. The Gdx machine is FDA approved for what we are using it for. This data was collected from patients as part of routine daily ophthalmology practice and was not collected for the purpose of a study. Patients underwent Gdx testing as part of a work up for glaucoma. This data was collected prior to the submission of this protocol and was stored in the hard drive on the Gdx computer in our clinic. "Subjects" consist of a Gdx printout on an 8.5 X 11 inch piece of paper. On this printout is displayed the nerve fiber analysis data for the eye of a patient being worked up for glaucoma (see attached figure). All patient identifiers are removed from the printout by the technician printing the Gdx image prior to giving the image to the principal investigator. d.Methodology: Three glaucoma specialists (experts in the field of glaucoma and the use of Gdx technology) will be asked to evaluate the efficacy and efficiency of receiving Gdx images via the Internet. This study is not designed to evaluate the Gdx machine or technology. This has been done by the company and has resulted in FDA approval of this device. This study is solely evaluating the feasibility of sending Gdx images to glaucoma specialists via the Internet. If the glaucoma specialists are able to receive and open the Gdx images via Internet in an efficient manner and the images are of sufficient quality than this study will show that using the Internet to transmit this data is feasible. If feasible than transmitting the data might allow the patient to stay in theater and not be air-evacuated to CONUS for an exam by a glaucoma specialist.

Remainder of excerpts placed in Life cycle due to space constaints.

PI's Problem Area Evaluation: : Project encountered some problem/issues

LIFE-CYCLE

Presently we are waiting for the glaucoma consultants to return their questionnaires for statistical analysis. Once statistical analysis is complete a final report of results will be generated in the form of an abstract that will be submitted to the funding authority. In addition the results will be presented at a minimum of one national meeting using previously allocated telemedicine funds.

Remainder of proposal change excerpts placed here:

Data Collection: See "Subjects" above. A Gdx image will be selected randomly from the hard drive and printed onto an 8.5" x 11" piece of paper using a color printer that comes with the Gdx machine. Three printouts of the same Gdx image will be made (so that one can be sent to each of the three examiners). This will be done for thirty different images. Each of the thirty images corresponds to the nerve fiber analysis of one eye of 30 patients who had been evaluated for glaucoma in our clinic. All patient identifiers direct and indirect (name and social security number) will be removed from the paper by an ophthalmic technician not involved with this study. The 3 copies of the 30 Gdx images will be given the principal investigator without patient identifiers. The thirty images will be numbered randomly from 1 to 30 for later data analysis. The thirty images will be scanned and saved as JPEG files (patient identifiers previously removed). Each of the thirty scanned Gdx images will be emailed via outlook to 3 different Active duty military glaucoma specialists who have agreed to participate as examiners in this study. They will be sent a questionnaire via email and be asked to evaluate each of the thirty Gdx emailed images and answer the questionnaire for each of the thirty Gdx emailed images. The 30 original hard copy color printouts of the Gdx images will then be mailed via the United States Postal Service to each of the three glaucoma specialists. After they answer the questions pertaining to the emailed Gdx images they will be asked to compare the emailed version of the Gdx image to the original color printout for the thirty Gdx images. They will be asked to answer the questionnaire pertaining to the comparison of the emailed Gdx images and the original Gdx color printouts. Please reference attached copy of questionnaire. The three examiners will mail the completed questionnaires to the principal investigator's institution where the three packages will be cleared of the identities of the reviewers (i.e return address removed) and labeled A, B, and C by an independent person not associated with the study. The "anonymous" packages will then be given to the principal investigator for data analysis. This ensures that the principal investigator is masked from knowing which reviewer send which package. This removes the "identifiers" with regard to the reviewers. The three examiners are from different institutions and will be asked not to discuss their scoring of the questionnaire with each other.

PI's Life-Cycle Evaluation: : Project encountered some problems/issues

DELIVERABLES

Study results in the form of a paper will be submitted. In addition the results will be presented at a national meeting. Since the protocol has been modified (see above and below) the results of the study will be in a slightly different format (see protocol).

Remainder of modified protocol pasted below:

Sample Size/Data Analysis: There will be 30 Gdx images being evaluated by 3 examiners who will compare the original to the emailed image. The questionnaire uses graded questions from 1-10 to allow for statistical analysis. The quality of the images assessed by the three raters will be summarized for each rater and as appropriate for all three raters by each question using descriptive statistics such as means and standard deviations. The agreement between the raters will be analyzed using Pearson correlation coefficients matrix. Repeated measures analysis of variance will be performed to determine the intra-class correlation coefficients among the three raters. For sample size estimation, assuming the standard deviation for the scale of 1 to 10 would be 2.5, a sample size of 30 images will provide a 95% confidence interval within +/- 0.89 for the mean score. Thus, a mean score >/= 8.0 will indicate good quality of the images after transmission with the lower bound of the 95% confidence interval >7.0. Also, the sample size of 30 images will show a good agreement for a correlation coefficient of >/= 0.83, where the 95% confidence interval has a lower bound >0.7.

PI's Deliverables Evaluation: : Deliverable is on schedule per Proposal

Expenditures

Element of Resource (EOR)	1ST Quarter Oct 1 - Dec 31	2nd Quarter Jan 1 - Mar 31
Travel 2100	$0.00	$0.00
Shipping 2200	$0.00	$0.00
Rent & Communications 2200	$0.00	$0.00
Contract for Services 2500	$0.00	$0.00
Supplies 2600	$0.00	$0.00
Equipment 3100	$0.00	$0.00

Financial Narrative:

No additional funds have been used since initial purchase of Gdx Nerve fiber layer analyzer. Future spending will be on TDY cost to present results at a national meeting.

PI's Financial Evaluation: : Deliverable is on schedule per Proposal

*** END OF REPORT ***